

# **CATHETER HAVING MULTIPLE SPINES EACH HAVING ELECTRICAL MAPPING AND LOCATION SENSING CAPABILITIES**

## **BACKGROUND OF THE INVENTION**

Electrophysiology catheters are commonly used for mapping electrical activity in a heart. Electrophysiology is a specialty within the field of cardiology for diagnosis and treatment of electrical abnormalities of the heart. By mapping the electrical activity in the heart, ectopic sites of electrical activation or other electrical activation pathways that contribute to heart malfunctions may be detected. This type of information may then allow a cardiologist to intervene and destroy the malfunctioning heart tissues. Such destruction of heart tissue is referred to as ablation, which is a rapidly growing field within electrophysiology and obviates the need for maximally invasive open heart surgery.

Attached to the electrophysiology catheters are electrodes, which are used to map, or collect electrical information about, the electrical activity in the heart. It is also known to incorporate into certain electrophysiology catheters a location or position sensor for determining the location of the electrodes being used to map the electrical activity in the heart. Such catheters are generally inserted percutaneously and fed through one or more major blood vessels into a chamber of the heart. A location sensor in the catheter, typically near the catheter's distal end, produces signals that are used to determine the position of the device relative to a frame of reference, such as a position external to the body or within the heart itself. The location sensor may be active or passive and may operate by generating or receiving electrical, magnetic or ultrasonic energy fields or other suitable forms of energy known in the art.

U.S. Patent No. 5,391,199, the disclosure of which is incorporated herein by reference, describes a position-responsive catheter comprising a miniature sensor coil contained in the catheter's distal end. The coil generates electrical signals in response to externally-applied magnetic fields, which are produced by field-generator coils placed outside the patient's body. The electrical signals are analyzed to determine the three-dimensional coordinates of the coil.

International Publication No. WO 96/05768, the disclosure of which is also incorporated herein by reference, describes a position-responsive catheter comprising a plurality of miniature, preferably non-concentric, sensor coils fixed in the catheter's distal end. As in Patent No. 5,391,1999, electrical signals generated by these coils in response to an externally-applied magnetic field are analyzed so as to determine, for example, the six-dimensional coordinates of these coils, i.e. the positional coordinates and the orientational coordinates.

Multiple position-sensing devices may be placed in a known, mutually-fixed spatial relation at or adjacent to the distal end of a catheter, as described, for example, in International Publication No. WO 97/24983, the disclosure of which is incorporated herein by reference. This publication describes a catheter having a substantially rigid structure at its distal end, to which one or more position sensors are fixed. The sensors are used to determine the position and orientation of the rigid structure.

## SUMMARY OF THE INVENTION

The present invention is directed to an improved catheter for mapping the electrical activity in a heart. The catheter comprises a plurality of spines each capable of obtaining electrical, mechanical and locational data.

In one embodiment, the invention is directed to a catheter comprising an elongated catheter body having proximal and distal ends and at least one lumen extending longitudinally therethrough. Mounted at the distal end of the catheter body is a mapping assembly having at least two spines, each having a proximal end attached at the distal end of the catheter body and a free distal end. Each spine comprises at least one location sensor and at least one electrode, preferably a tip electrode and at least one ring electrode.

In a preferred embodiment, the invention is directed to a catheter comprising an elongated catheter body having proximal and distal ends and at least one lumen longitudinally extending therethrough. Mounted at the distal end of the catheter body is a mapping assembly having at least two spines, each having a proximal end attached at the distal end of the catheter body and a free distal end. Each spine comprises at least one location sensor, at least one electrode, and a non-conductive covering having a support arm that has shape memory. Preferably, each spine comprises a tip electrode and at least one ring electrode. The mapping assembly is moveable between an expanded arrangement, in which each spine extends radially outward from the catheter body and a collapsed arrangement, in which each spine is disposed generally along a longitudinal axis of the catheter body. In use, at least one electrode from each spine may be positioned in contact with heart tissue to map the electrical activity of the heart. The location sensors may be used to determine the location of the electrodes at each instance when the electrodes are obtaining electrical activity data.

# DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of a catheter according to the invention.

FIG. 2 is a side cross-sectional schematic view of a portion of the catheter of FIG. 1, taken from line 2-2 in FIG. 1.

FIG. 3 is an end cross-sectional view of a portion of the catheter of FIG. 1, taken from line 3-3 in FIG. 2.

FIG. 4 is a side cross-sectional schematic view of one of the spines of the catheter of FIG. 1, taken from line 4-4 in FIG. 1.

FIG. 5 is an end cross-sectional view of the tip electrode of the spine of FIG. 4, taken from line 5-5 in FIG. 4.

FIG. 6 is a perspective view of a pigtail dilator useful for introduction of the catheter of FIG. 1 into a patient.

FIG. 7 is a perspective view of an alternative embodiment of an expanded arrangement of the mapping assembly of a catheter according to the invention.

FIG. 8 is a perspective view of another alternative embodiment of an expanded arrangement of the mapping assembly of a catheter according to the invention.

## DETAILED DESCRIPTION OF THE INVENTION

The invention is directed to a catheter having a mapping assembly comprising a plurality of spines. Each spine carries at least one location sensor and at least one electrode, preferably a tip electrode and at least one ring electrode, such that when the spines are positioned in contact with heart tissue, each spine is capable of obtaining electrical, mechanical and locational data. As shown in FIG. 1, the catheter **10** comprises an elongated catheter body **12** having proximal and distal ends, a control handle **16** at the proximal end of the catheter body **12**, and a mapping assembly **18** comprising a plurality of spines **14** mounted at the distal end of the catheter body **12**.

As shown in FIGs. 1 and 2, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **15**, but can optionally have multiple lumens along all or part of its length if desired. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction of the catheter

body 12 comprises an outer wall 13 made of polyurethane or PEBAX® (polyether block amide). The outer wall 13 comprises an imbedded braided mesh of stainless steel or the like, as is generally known in the art, to increase torsional stiffness of the catheter body 12 so that, when the control handle 16 is rotated, the distal end of the catheter body 12 will rotate in a corresponding manner.

The length of the catheter body 12 is not critical, but preferably ranges from about 90 cm to about 120 cm, and more preferably is about 110 cm. The outer diameter of the catheter body 12 is also not critical, but is preferably no more than about 8 french, more preferably about 7 french. Likewise, the thickness of the outer wall 13 is not critical, but is preferably thin enough so that the central lumen 15 can accommodate puller wires, lead wires, sensor cables and any other wires, cables or tubes. If desired, the inner surface of the outer wall 13 is lined with a stiffening tube (not shown) to provide improved torsional stability. An example of a catheter body construction suitable for use in connection with the present invention is described and depicted in U.S. Patent No. 6,064,905, the entire disclosure of which is incorporated herein by reference.

In the depicted embodiment, the mapping assembly 18 comprises five spines 14. Each spine 14 has a proximal end attached at the distal end of the catheter body 12 and a free distal end, i.e., the distal end is not attached to any of the other spines, to the catheter body, or to any other structure that confines movement of the distal end. Each spine 14 contains a support arm 24 comprising a metal or plastic material that has shape memory, such that the support arm 24 forms an initial shape when no external forces are applied, forms a deflected shape when an external force is applied, and returns to its initial shape when the external force is released. In a preferred embodiment, the support arm 24 comprises a superelastic material, for example a nickel-titanium alloy, such as Nitinol. Each spine 14 also comprises a non-conductive covering 26 in surrounding relation to the support arm 24. In a preferred embodiment, the non-conductive covering 26 comprises a biocompatible plastic tubing, such as a polyurethane or polyimide tubing.

As will be recognized by one skilled in the art, the number of spines 14 can vary as desired depending on the particular application, so that the catheter 10 has at least two spines, preferably at least three spines, more preferably at least five spines and as many as eight or more spines. As described in more detail below, the spines 14 are moveable between an expanded arrangement, wherein, for example, each spine extends radially outwardly from the catheter body 12, or the spines 14 may be arranged in a collapsed arrangement, wherein, for example,

each spine is disposed generally along a longitudinal axis of the catheter body 12 so that the spines are capable of fitting within a lumen of a guiding sheath, as discussed further below.

Each spine 14 carries at least one electrode mounted along its length, preferably at or near its distal end. In the depicted embodiment, a tip electrode 20 is mounted on a distal end of each non-conductive covering 26 and at least one ring electrode 28 is mounted on each non-conductive covering 26, preferably on the distal end of the non-conductive covering 26. In this bipolar arrangement, the ring electrode 28 is used as a reference electrode. The distance between the tip electrode and ring electrode preferably ranges from about 0.5 mm to about 2 mm. In an alternative bipolar arrangement (not shown), the tip electrode 20 is eliminated and at least two ring electrodes 28 are mounted on each non-conductive covering 26, preferably on the distal end of the non-conductive covering 26. Another alternative embodiment (not shown), is a unipolar arrangement, in which the tip electrode 20 is mounted on the distal end of each non-conductive covering 26, with one or more reference ring electrodes mounted on the distal end of the catheter body 12, or one or more reference electrodes attached outside the body of the patient (e.g., in the form of a patch). In an alternative unipolar arrangement, a ring electrode 28 mounted on each non-conductive covering 26, preferably on the distal end of the non-conductive covering 26, is used instead of a tip electrode 20.

Each tip electrode 20 has an exposed length preferably ranging from about 0.5 mm to about 4 mm, more preferably from about 0.5 mm to about 2 mm, still more preferably about 1 mm. Each ring electrode 28 has a length preferably up to about 2 mm, more preferably from about 0.5 mm to about 1 mm.

Each tip electrode 20 and each ring electrode 28 is electrically connected to an electrode lead wire 29, which in turn is electrically connected to a connector 17. The connector 17 is connected to an appropriate mapping or monitoring system (not shown). Each electrode lead wire 29 extends from the connector 17, through the control handle 16, through the central lumen 15 in the catheter body 12, and into the non-conductive covering 26 of the spine 14 where it is attached to its corresponding tip electrode 20 or ring electrode 28. Each lead wire 29, which includes a non-conductive coating over almost all of its length, is attached to its corresponding tip electrode 20 or ring electrode 28 by any suitable method.

A preferred method for attaching a lead wire 29 to a ring electrode 28 involves first making a small hole through an outer wall of the non-conductive covering 26. Such a hole can be created, for example, by inserting a needle through the non-conductive covering 26 and heating the needle sufficiently to form a permanent hole. The lead wire 29 is then drawn through

the hole by using a microhook or the like. The end of the lead wire **29** is then stripped of any coating and welded to the underside of the ring electrode **28**, which is then slid into position over the hole and fixed in place with polyurethane glue or the like. Alternatively, each ring electrode **28** may be formed by wrapping the lead wire **29** around the non-conductive covering **26** a number of times and stripping the lead wire of its own non-conductive coating on its outwardly facing surfaces. In such an instance, the lead wire **29** functions as a ring electrode.

Each spine **14** also includes at least one location sensor **30**. The location sensor **30** is mounted near the distal end of each spine. In the depicted embodiment, where each spine **14** comprises a tip electrode **20**, a location sensor **30** is mounted such that the distal end of the location sensor **30** is secured within its corresponding tip electrode **20**, while the proximate end of the location sensor **30** extends into the distal end of the non-conductive covering **26**. Each location sensor **30** is used to determine the coordinates of its corresponding tip electrode **20** at each instant when the tip electrode **20** is being used to collect an electrical mapping data point. As a result, both electrical and locational data can be obtained for each data point that is mapped. If the spine **14** carries at least one ring electrode **28** but does not include a tip electrode **20**, the location sensor **30** is mounted near the distal end of the non-conductive covering **26**, preferably as close to the distal end of the spine **14** as possible or in a plane concentric with the ring electrode **28**.

Each location sensor **30** is connected to a corresponding sensor cable **36**. Each sensor cable **36** extends through the non-conductive covering **26**, catheter body **12** and control handle **16** and out the proximal end of the control handle **16** within an umbilical cord (not shown) to a sensor control module (not shown) that houses a circuit board (not shown). Alternatively, the circuit board can be housed within the control handle **16**, for example, as described in U.S. Patent No. 6,024,739, the disclosure of which is incorporated herein by reference. Each sensor cable **36** comprises multiple wires encased within a plastic covered sheath. In the sensor control module, the wires of the sensor cable **36** are connected to the circuit board. The circuit board amplifies the signal received from the corresponding location sensor **30** and transmits it to a computer in a form understandable by the computer by means of a sensor connector at the proximal end of the sensor control module. Also, because the catheter **10** is designed for single use only, the circuit board preferably contains an EPROM chip that shuts down the circuit board approximately twenty-four hours after the catheter **10** has been used. This prevents the catheter **10**, or at least the location sensors **30**, from being used twice.

Preferably each location sensor **30** is an electromagnetic location sensor. For example, each location sensor **30** may comprise a magnetic-field-responsive coil, as described in U.S. Patent No. 5,391,199, or a plurality of such coils, as described in International Publication WO 96/05758. The plurality of coils enables the six-dimensional coordinates (i.e. the three positional and the three orientational coordinates) of the location sensor **30** to be determined. Alternatively, any suitable location sensor known in the art may be used, such as electrical, magnetic or acoustic sensors. Suitable location sensors for use with the present invention are also described, for example, in U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, and 5,568,809, and International Publication Nos. WO 95/02995, WO 97/24983, and WO 98/29033, the disclosures of which are incorporated herein by reference. A particularly preferred location sensor **30** is a single axis sensor having a length ranging from about 3 mm to about 7 mm, preferably about 4 mm, such as that described in the U.S. Patent Application Serial No. 09/882,125 filed June 15, 2001, entitled "Position Sensor Having Core with High Permeability Material," the disclosure of which is incorporated herein by reference. Smaller sensors are particularly desirable for use in the present invention because of the need to keep the diameters of the spines **14** small enough so that they all fit within the lumen of a guiding sheath.

FIGs. 4 and 5 illustrate a suitable technique for mounting the electrode lead wire **29**, the location sensor **30** and the support arm **24** to the tip electrode **20**. The electrode lead wire **29** may be secured to the tip electrode **20** by drilling a first blind hole **48**, preferably a bore hole, into the tip electrode **20**, stripping the lead wire **29** of any coating and placing the lead wire **29** within the first blind hole **48** where it is electrically connected to the tip electrode **20** by a suitable means, such as by soldering or welding. The lead wire **29** may then be fixed in place, for example, by using a polyurethane glue or the like. The location sensor **30** may be similarly affixed to the tip electrode **20**. For example, a second blind hole **50**, preferably a bore hole, may be drilled into the tip electrode **20** such that the location sensor **30** may be inserted into the second blind hole **50** and affixed therein, for example, using a polyurethane glue or the like. The support arm **24** may also be similarly affixed to the tip electrode **20**. For example, a third blind hole **52**, preferably a bore hole, may be drilled into the tip electrode **20** such that the support arm **24** may be inserted into the third blind hole **52** and affixed therein, for example, using a polyurethane glue or the like. Alternatively, a single blind hole (not shown) in the proximal end of the tip electrode **20** can be used for mounting the location sensor **30** and support arm **24**, and the distal end of the lead wire **29** can be wrapped around the outside proximal end of the tip electrode, which is not

exposed and attached by solder, welding or any other suitable technique. Any other arrangement for mounting these components in the spine could also be used.

A suitable construction of the distal end of the catheter body **12**, having spines **14** mounted thereto, is depicted in FIGs. 2 and 3. For clarity, only two spines **14** are shown in FIG. 2. Mounted in the distal end of the lumen **15** of the catheter body **12** is a spine mounting assembly **31**. The spine mounting assembly **31** comprises an outer mounting ring **32** disposed within the outer wall **13** of the catheter body **12**. The outer mounting ring **32** preferably comprises a metal material, such as stainless steel, more particularly stainless steel 303, and may be attached at the distal end of the catheter body **12** by a variety of methods, such as by welding or by use of an adhesive, such as a polyurethane glue. Alternatively, the outer mounting ring **32** may comprise a plastic material. A mounting structure **34** is provided coaxially within the outer mounting ring **32**. In the depicted embodiment, the mounting structure **34** is multi-sided and comprises a metal material, such as stainless steel, more particularly stainless steel 303. The mounting structure **34** may also alternatively comprise a plastic material. The outer mounting ring **32** and the mounting structure **34** provide a channel **38** in which the proximal end of each support arm **24** is mounted. Specifically, each spine **14** is mounted in the catheter body **12** by removing a portion of the non-conductive covering **26** at the proximal end of each spine **14**, inserting the distal end of each support arm **24** into the channel **38** between the outer mounting ring **32** and the multi-sided mounting structure **34** and affixing each support arm **24** within the channel **38** by any suitable means, such as with a polyurethane glue or the like.

In a preferred embodiment, the support arm **24** has a generally trapezoidally-shaped end cross section with curved sides. In such an arrangement, when each support arm **24** is inserted into the channel **38**, a substantially flat surface of each support arm **24**, preferably the base of the trapezoidally-shaped end cross section, is mounted against a substantially flat surface on the multi-sided mounting structure **34**. Preferably the number of substantially flat outer surfaces on the multi-sided mounting structure **34** corresponds to the number of spines **14**. In such an instance, the support arm **24** of each spine **14** may be mounted within the channel **38** and adjacent to its corresponding side on the multi-sided mounting structure **34** to enable the support arms **24**, and thus the spines **14**, to be equally spaced around the multi-sided mounting structure **34**. The multi-sided mounting structure **34** may be approximately co-axial with the longitudinal axis of the catheter body **12** such that the spines **14** are equally spaced about the catheter body **12** as well. Once each support arm **24** is properly positioned within the channel **38**, each support arm **24** may be affixed within the channel **38** by any suitable means, such as by use of an adhesive, such as



a polyurethane glue. Alternatively, the mounting structure 34 can have a round outer surface, although with such an embodiment more care needs to be taken if the support arms 24 are to be evenly spaced about the mounting structure.

In the depicted embodiment, a first non-conducting tube 40 is disposed between the outer mounting ring 32 and the support arms 24, and a second non-conducting tube 42 is disposed between the support arms 24 and the mounting structure 34. The non-conducting tubes 40 and 42, which may be polyimide tubes, ensure that each support arm 24 remains electrically isolated. In addition, a mounting ring inner tube 44 is secured within the mounting structure 34. The mounting ring inner tube 44 preferably comprises a non-conducting material such as polyimide. The mounting ring inner tube 44 defines a mounting ring lumen 46 through which each of the electrode lead wires 29 and sensor cables 36 extend.

As previously discussed, when mounting the support arms 24 to the spine mounting assembly 31, a portion of the non-conductive covering 26 at the proximal end of each spine 14 is removed to expose the support arm 24. Removing a portion of the non-conductive covering 26 at the proximal end of each spine 14 enables the electrode lead wires 29 and sensor cables 36, corresponding to each tip electrode 20, ring electrode 28 and location sensor 30, to extend from the lumen 15 of the catheter 12, through the mounting ring lumen 46, and into each non-conductive covering 26. As shown in FIG. 4, once inserted into the non-conductive coverings 26, the electrode lead wires 29 and sensor cables 36 extend within the non-conductive covering 26 and are electrically connected at their distal ends to their corresponding tip electrode 20, ring electrode 28 or location sensor 30.

To use the catheter 10 of the invention, a cardiologist or electrophysiologist introduces a guiding sheath and a dilator into the patient, as is generally known in the art, so that the distal ends of the sheath and dilator are in the region of the heart to be mapped. In some instances, such as when it is desired to insert the catheter 10 into the left ventricle through the aortic valve in a direction opposite the blood flow, it is preferable to use a pigtail-shaped dilator 54 having a distal end 56 that forms a loop 58, as shown in FIG. 6. Specifically, the side of the loop 58 is pushed against the flaps of the valve and serves essentially as a blunt instrument to push the flaps inward so that they are temporarily inverted while the dilator and guiding sheath are advanced through the valve. By using the surface of the loop 58 to push the flaps of the valve, potential puncturing of the flaps of the valve can be avoided. In contrast, pushing the flaps with a dilator having a straight distal end can potentially puncture or otherwise damage the flaps. After the dilator and

guiding sheath having been advanced through the valve with the loop **58** inside the left ventricle, the flaps of the aortic valve return to their original, natural position.

Thereafter, the dilator is removed from the guiding sheath, and the catheter **10** is introduced into the patient through the guiding sheath. To insert the catheter **10** into the guiding sheath, the mapping assembly **18** must be in its collapsed arrangement, wherein each spine **14** is disposed generally along the longitudinal axis of the catheter body **12**. A suitable guiding sheath for use in connection with the catheter **10** is the PREFACE™ Braided Guiding Sheath (commercially available from Biosense Webster, Inc., Diamond Bar, California). Such a guiding sheath has sufficient strength to hold each support arm **24** in the collapsed arrangement, such that the spines **14** and also the entire remainder of the catheter **10** can travel within the guiding sheath, from an insertion point in the patient, through a vein or artery and to a desired location in the heart. Once the distal end of the catheter has reached the desired location, such as a position within the left ventricle of the heart, relative longitudinal movement between the catheter **10** and the guiding sheath is provided to allow at least a portion of each spine **14** to protrude from the guiding sheath. Preferably the guiding sheath is moved proximally relative to the distal end of the catheter to expose the spines **14**. When a portion of each spine **14** protrudes from the guiding sheath and a compression force is no longer applied by the guiding sheath on the spines, the shape memory of the support arms **24** allows the support arms to revert to a first expanded arrangement. In the first expanded arrangement, at least one electrode from each spine **14** can be placed into contact with a first plurality of the heart tissue such that electrical, locational and mechanical information can be obtained from the contacted heart tissue. The spines **14** can then be repositioned to a second expanded arrangement to contact a second plurality of heart tissue such that electrical, locational and mechanical information can be obtained from these tissues as well. This repositioning is preferably achieved by further moving the guiding sheath proximally relative to the catheter to thereby expose a greater portion of each spine. In the depicted embodiment, the more of each spine that is exposed, the further each spine can bend or expand away from the catheter to thereby contact heart tissue. This process can be repeated until the heart has been satisfactorily mapped.

The expanded arrangement of spines **14** can take on various shapes. For instance, in the above-described embodiment, each spine **14** extends radially outwardly from the catheter body **12** and forms an outwardly curved shape as shown in FIG. 1. In another embodiment, shown in FIG. 8, each spine **14** extends radially outwardly from the catheter body **12** and forms a substantially straight line, which is preferably substantially perpendicular to the catheter

body 12. In still another embodiment, shown in FIG. 7, each spine 14 bows radially outwardly such that the spines 14, taken together, form a cup shape.

Using the inventive catheter 10 having multiple spines 14, each having electrical and mechanical mapping and locational sensing capabilities, the cardiologist can map local activation time and obtain voltage maps. The cardiologist can also determine those locations in the heart having no mechanical activity by monitoring whether the position of the location sensor changes over a complete cardiac cycle. This information can guide the cardiologist in providing therapy to the patient. For example, where the cardiologist finds regions of the heart that do not have mechanical activity, he or she can revascularize those regions using known techniques, such as gene therapy or transmyocardial revascularization. The inventive catheter 10 allows the cardiologist to map the heart more quickly than traditional catheters by measuring multiple points of data at a time.

If desired, the catheter may include a steering mechanism for deflection of the distal end of the catheter body 12. With such a design, the distal end of the catheter body 12 preferably comprises a short length of tubing, e.g., 2 to 4 inches in length, that is more flexible than the remainder of the catheter body 12. A suitable steering mechanism comprises a puller wire (not shown) that extends from a proximal end in the control handle 16, through the central lumen 15 in the catheter body 12 and into an off axis lumen in the short length of tubing. Within the catheter body 12, the puller wire extends through a closely wound coil that is bendable but substantially non-compressible. The coil is fixed near the proximal and distal ends of the catheter body 12 and prevents deflection of the catheter body 12. The distal end of the puller wire is anchored at the distal end of the short length of tubing in the off axis lumen. The proximal end of the puller wire is anchored to a movable member in the handle 16 that can be moved relative to the catheter body 12. Proximal movement of the movable member relative to the catheter body 12 results in deflection of the short length of tubing. An example of such a steering mechanism and construction is described in more detail in U.S. Patent No. 6,064,905, the disclosure of which is incorporated herein by reference. When incorporating a steering mechanism into the inventive catheter 10, it may be desirable to include a location sensor at the distal end of the catheter body 12. As would be recognized by one skilled in the art, of a slurring mechanism is not including, the handle 16 can be eliminated, although it is described to maintain the handle for ease of use by the cardiologist.

The preceding description has been presented with references to presently preferred embodiments of the invention. Persons skilled in the art and technology to which this invention

pertains will appreciate that alterations and changes in the described structures can be practiced without meaningfully departing from the principle, spirit and scope of this invention.

5 Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and shown in the accompanying drawings, but rather should be read as consistent with and as support for the following claims, which are to have their fullest and fairest scope.

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